REGULATION 9 —PHARMACEUTICAL CARE/PATIENT COUNSELING

09-00: PATIENT COUNSELING

09-00-0001--PATIENT INFORMATION, DRUG USE EVALUATION, AND PATIENT COUNSELING

The intent of this regulation is to improve pharmaceutical care by defining basic standards of care. Pharmacy care/pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: (1) cure of disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing a disease process, or (4) preventing a disease or symptomatology.

Pharmaceutical care (clinical pharmacy) involves four major functions on behalf of the patient: (1) identifying potential and actual drug-related problems, (2) resolving actual drug related problems, (3) preventing potential drug-related problems, and (4) optimizing patient therapy outcomes. It is recognized that the patient might be best served if medication is not provided.

a. Patient information (profile)

In order to effectively counsel patients, the pharmacist must, through communication with the patient or caregiver, make a reasonable effort to obtain, record, and maintain the following information for each patient. It is recognized that most of this can be obtained using "qualified pharmacy employees" and designed forms, etc.

(1) Name, address, telephone number;
(2) Date of birth (age);
(3) Gender;
(4) Medical history
  (A) Significant patient health problems known to the pharmacist;
  (B) Prescription drug reactions/prescription drug allergies;
  (C) List of prescription medications and legend drug administration devices known to the pharmacist.
(5) Transitory patients or situations where the pharmacy will only provide medication one time
  In obtaining patient information, if the pharmacist knows or is informed by the patient that this is a one-time situation, the pharmacist may forego the above requirement to record and maintain the information.
(6) Pharmacist comments

(b) Drug use evaluation for new and refill prescriptions

Drug use evaluation or drug utilization review includes the following activities:

(1) The pharmacist shall evaluate the prescription or medication order for:
  (A) Reasonable dose and route of administration;
  (B) Reasonable directions for use.
(2) The pharmacist shall evaluate medication orders and patient information for:
  (A) Duplication of therapy - is the patient taking same or similar medication(s)?;
  (B) Prescription drug-prescription drug interactions;
  (C) Proper utilization (over or under utilization);
  (D) Known drug allergies.

(3) Drug-drug contraindications as defined by the Board. (Is this medication contraindicated with another medication the patient is taking?)
(4) It is recognized that the ultimate decision to use the medication or not use the medication rests with the physician who has more complete patient information. It is the pharmacist's responsibility to monitor the patient's medication therapy in the areas addressed in this regulation and inform the physician of the suspected problem.
(5) If a problem is suspected and the physician is informed, the pharmacist shall document the process.

(c) Patient counseling.
(1) A pharmacist shall counsel the patient or caregiver "face to face" if the patient or caregiver is in the pharmacy. If not, a pharmacist shall make a reasonable effort to counsel the patient or caregiver;
(2) Alternative forms of patient information may be used to supplement, but not replace face-to-face patient counseling;
(3) Patient counseling, as described herein, shall also be required for outpatients of hospitals and institutions when medications are dispensed on discharge from the hospital or institution.
(4) Patient counseling as described in this regulation shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer the medication. However, the pharmacist shall provide drug therapy counseling when professionally deemed to be appropriate and when medications are provided by the pharmacy, when a pharmacist is on duty and a patient is discharged from the hospital or institution.
(5) The pharmacist shall maintain and make available to all patients appropriate patient-oriented reference materials USP-DI or *Facts and Comparisons Patient Drug Facts* or an equivalent or better publication as determined by the Board.
(6) It is recognized that the ultimate decision to not provide patient counseling rests with the physician. If the physician in specific instances (blanket requests not accepted) requests that information NOT be provided to the patient and gives reason, the pharmacist should honor that request in almost all instances.

(d) "Patient counseling" shall mean the effective communication by the pharmacist of information, as defined in this act to the patient or caregiver, in order to improve therapeutic outcome by encouraging proper use of prescription medications and drug delivery devices.
(1) For original prescription medication orders, (excluding renewed or updated prescriptions the patient has been recently taking) and orders for legend devices, specific areas of counseling shall include:
(A) Name and general description of the medication dispensed, i.e. antibiotic, antihistamine, blood pressure medicine, etc.
(B) Name, general description and directions for use of drug delivery devices, i.e., insulin syringes, morphine pump, etc.
(C) Explanation of route of administration, dosage, times of administration, and continuity of therapy;
(D) Special directions for storage as deemed necessary by the pharmacist;
(E) If the drug has been determined to have a significant side effect by the Board of Pharmacy, the patient shall be properly counseled to the extent deemed necessary by the pharmacist.

(F) When the prescription drug dispensed has a significant side effect, if taken with over-the-counter drugs, the pharmacist should counsel the patient about that interaction. (Example: coumadin with aspirin)

(G) If the prescription medication is significantly affected by food or diet, the pharmacist should so advise the patient. (Example: tetracycline with milk or food)

(H) The pharmacist shall inform the patient or caregiver that he/she is available to answer questions about medications or general health information.

(2) Refills--On refills the pharmacist shall present the opportunity for the patient or caregiver to ask questions. However, counseling on refills is not required except when needed in the professional judgment of the pharmacist.

(d) Drug interactions – significant side effects

Recognizing that a pharmacist cannot be expected to recognize all possible drug interactions and also recognizing that the pharmacist and the patient does not have time to explain the numerous side effects of drugs, the pharmacy shall maintain a computer program which will identify significant drug interactions. (These are drugs with side effects which may be managed most effectively if the patient is aware of the specific side effect and what to do if it occurs.) The pharmacist in charge will be responsible for assuring that the computer system adequately flags and warns the pharmacist of any occurrence of significant drug interactions or significant side effects. (If a pharmacy was in business before September 1, 1997, and at that time, did not have a computer system, said pharmacy may substitute *Patient Drug Facts* or other drug interaction manuals to reference drug interactions and side effects for effective patient counseling. This method should only be used until such time as the pharmacy acquires an adequate computer program as described in this section.)

The pharmacist will be responsible for counseling the patient on these interactions with verbal and, where appropriate, written information. (2/12/91, 2/10/98)

09-00-0002—PRESCRIPTION ORDERS TO ADMINISTER MEDICATION AND/OR IMMUNIZATIONS

(a) Medications Administration Advisory Committee:

(1) The purpose of the Medication Administration Advisory Committee shall include functioning in an advisory capacity to assist the Board with implementation and oversight of the provisions regarding medication administration authority.

(2) The Medication Administration Advisory Committee shall be composed of five members, to be approved by the Governor, who have the following qualifications:

(A) Two members shall be licensed physicians selected from a list of three names per position submitted jointly by the State Medical Board and the Arkansas Medical Society.

(B) Two members shall be licensed pharmacists-- one pharmacist shall be recommended by the Arkansas Pharmacists Association and one pharmacist shall be a member of the Arkansas State Board of Pharmacy.

(C) One member shall be an advanced practice nurse holding a certificate of prescriptive authority selected from a list of three names submitted jointly by the State Nursing Board and the Arkansas Nurses Association.

(D) The Board may remove any advisory committee member, after notice and hearing for incapacity, incompetence, neglect of duty, or malfeasance in office.

(E) The members shall serve without compensation, but may be reimbursed to the extent special moneys are appropriated therefore for actual and necessary expenses incurred in the performance of their duties.

(3) The five initial members appointed to the committee shall draw lots to determine staggered lengths of their initial terms. Successive members shall serve three (3) year terms.

(b) Authority for pharmacists to administer medications/immunizations:

(1) Pharmacists may provide pharmaceutical care to patients over the age of eighteen (18) by administering medications or immunizations to an eligible patient upon a valid prescription order by a practitioner so authorized to prescribe such medications or immunizations. A prescription order for a medication or immunization shall constitute a unique class of prescriptions and shall apply to any person over the age of eighteen (18) desiring a medication or immunization. A prescription from a practitioner for administration, by a pharmacist, of an approved medication or immunization will be known as an "Authority to Administer."

(2) An Authority to Administer, once granted, is valid for a time period not to exceed one (1) year--unless such an order is invalidated by the practitioner granting the authority.

(3) An Authority to Administer is valid only for the pharmacist meeting the requirements set forth by the Arkansas State Board of Pharmacy and is not transferable.

(4) Unless otherwise specifically authorized by the Board, a person must possess the following qualifications to be qualified to accept an initial Authority to Administer order:

(A) obtain and maintain a license to practice pharmacy issued by the Arkansas State Board of Pharmacy;

(B) successfully complete a Board approved course of study, examination, and certification consisting of a training program that includes the current guidelines and recommendations of the Centers of Disease Control and Prevention. The course of study should include, at a minimum:

(i) basic immunology, including the human immune response;

(ii) the mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication/immunization;

(iii) how to handle an emergency situation in the event one should arise as a result of the administration of the medication /immunization;

(iv) how to persuade patients to be immunized and options for record keeping for patients that do get immunized;

(v) how to administer subcutaneous, intradermal, and intramuscular injection; and

(vi) record keeping requirements for these medications as required by law or regulation.

(C) obtain supervised instructions on the physical administration of vaccines during such course of study and certification;

(D) obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS); and

(E) successfully complete the above described course of study which shall be a minimum of twenty (20) hours and shall qualify for continuing education credits. The provider of said course of study shall provide participants a certificate of completion which shall be displayed in the pharmacy at which the pharmacist is working. A copy of said

certificate shall be mailed to the Board of Pharmacy offices and placed in the pharmacist's permanent file.

(5) Continuing competency for certification for Authority to Administer must be maintained. A minimum of one (1) hour of the fifteen (15) hour requirement for continuing education, every year, must be dedicated to this area of practice.

(6) An Authority to Administer order shall meet the following requirements:
   (A) must properly identify the practitioner issuing the order;
   (B) must identify the medication or vaccine covered in any such order;
   (C) must properly identify the patient to receive any medication or immunization, by name, address, age, sex, and date of administration;
   (D) must identify the medication or vaccine administered, site of the administration, dose administered, identity of pharmacist administering the dose; and
   (E) must bear the date of the original order and the date of each administration.

(e) Seven classifications of approved medications for administration
   (1) Immunizations
   (2) Vaccines
   (3) Allergy medications
   (4) Vitamins
   (5) Minerals
   (6) Antihyperglycemics
   (7) Anti-nausea medications

09-00-0003—REQUIREMENTS FOR DIABETES SELF-MANAGEMENT TRAINING FOR PHARMACISTS

In order to be certified to provide Diabetes Self-Management Training, a pharmacist shall complete an educational program, which is approved by the Arkansas State Board of Pharmacy and in compliance with the National Standards for Diabetes Self-Management Education as developed by the American Diabetes Association.

The standards for the educational program are as follows:

(a) The sponsoring organization shall have a written policy that affirms education as an integral component of diabetes care.

(b) The sponsoring organization shall identify and provide the educational resources required to achieve its educational objectives in terms of its target population. These resources include adequate space, personnel, budget, and instructional materials.

(c) The organizational relationships, lines of authority, staffing, job descriptions, and operational policies shall be clearly defined and documented.

(d) The service area shall be assessed in order to define the target population and determine appropriate allocation of personnel and resources to serve the educational needs of the target population.

(e) A standing advisory committee consisting of a pharmacist, physician, nurse educator, dietician, and individual with behavioral science expertise, a consumer, and a community representative, at a minimum shall be established to oversee the program.

(f) The advisory committee shall participate in the annual planning process, including determination of target audience, program objective, participant access mechanisms, instructional methods, resource requirements (including space, personnel, budget, and materials), participant follow up mechanisms, and program evaluation.

(g) Professional program staff shall have sufficient time and resources for lesson planning, instruction, documentation, evaluation, and follow-up.
(h) Community resources shall be assessed periodically.
(i) A coordinator shall be designated who is responsible for program planning, implementation, and evaluation.
(j) Health care professionals with recent didactic and experiential preparation in diabetes clinical and educational issues shall serve as the program instructors. The staff shall include at least a nurse educator and a dietician who collaborate routinely. Certification as a diabetes educator by the National Certification Board for Diabetes Educators is recommended.
(k) Professional program staff shall obtain education about diabetes educational principles and behavioral change strategies on a continuing basis.
(l) Based on the needs of the target population, the program shall be capable of offering instruction in the following content areas:
    (1) Diabetes overview
    (2) Stress and psychosocial adjustment
    (3) Family involvement and social support
    (4) Nutrition
    (5) Exercise and activity
    (6) Medications
    (7) Monitoring and use of results
    (8) Relationship among nutrition, exercise, medication, and blood glucose levels
    (9) Prevention, detection, and treatment of acute complications
    (10) Prevention, detection, and treatment of chronic complication
    (11) Foot, skin, and dental care
    (12) Behavior change strategies, goal setting, risk factor reduction, and problem solving
    (13) Benefits, risks, and management options for improving glucose control
    (14) Preconception care, pregnancy, and gestational diabetes
    (15) Use of health care systems and community resources
(m) The program shall use instructional methods and materials that are appropriate for the target population and the participants being served.
(n) A system shall be in place to inform the target population and potential referral sources of the availability and benefits of the program.
(o) The program shall be conveniently and regularly available.
(p) The program shall be responsive to requests for information and referrals from consumers, health care professionals, and health care agencies.
(q) An individualized assessment shall be developed and updated in collaboration with each participant. The assessment shall include relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors.
(r) An individualized education plan, based on the assessment, shall be developed in collaboration with each participant.
(s) The participant's educational experience, including assessment, intervention, evaluation, and follow-up, shall be documented in a permanent medical or education record. There shall be documentation of collaboration and coordination among program staff and other providers.

(t) The program shall offer appropriate and timely educational interventions based on periodic reassessments of health status, knowledge, skills, attitudes, goals, and self-care behaviors.
(u) The advisory committee shall review program performance annually, including all components of the annual program plan and curriculum, and use the information in subsequent planning and program modification.
(v) The advisory committee shall annually review and evaluate predetermined outcomes for program participants.

09-00-0004—DRUG THERAPY MANAGEMENT BY A PHARMACIST UNDER WRITTEN PROTOCOL OF A PHYSICIAN

The purpose of this regulation is to provide standards for the maintenance of records of a pharmacist engaged in the provision of drug therapy management as authorized in §17-92-101 (16) and §17-92-205 (a).

(a) Definitions. The following words and terms, when used in this regulation, shall have the following meanings, unless the context clearly indicates otherwise:
  (1) "Act" means the Arkansas Pharmacy Practice Act
  (2) "Board" means the Arkansas State Board of Pharmacy
  (3) "Confidential record" means any health-related record maintained by a pharmacy or pharmacist--such as a patient medication record, prescription drug order, or medication order.
  (4) "Drug therapy management" means the performance of specific acts of drug therapy management delegated to a pharmacist for an individual patient by an authorized practitioner through written protocol. (Drug therapy management shall not include the selection of drug products not prescribed by the practitioner, unless the drug product is named in the practitioner initiated protocol.)
  (5) "Written protocol" means a practitioner's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Arkansas State Medical Board under the Medical Practice Act.
    (A) A written protocol must contain at a minimum the following:
      (i) A statement identifying the individual practitioner authorized to prescribe drugs and responsible for the delegation of drug therapy management;
      (ii) A statement identifying the individual pharmacist authorized to dispense drugs and to engage in drug therapy management delegated by the practitioner;
      (iii) A statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:
        (a) A statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and
        (b) A specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority
      (iv) A statement of the activities the pharmacist shall follow in the course of exercising drug therapy management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) A statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated drug therapy management and the results of the drug therapy management.

(B) A standard protocol may be used, or the attending practitioner may develop a drug therapy management protocol for the individual patient. If a standard protocol is used, the practitioner shall record, what deviations if any, from the standard protocol are ordered for that patient;

(C) Maintenance of records:

(i) Every patient record required to be kept under this regulation shall be kept by the pharmacist and be available, for at least two (2) years from the date of such record, for inspecting and copying by the Board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(ii) Patient records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(a) The records maintained in the alternative system contain all of the information required on a manual record; and

(b) The data processing system is capable of producing a hard copy of the record upon the request of the Board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(D) Written protocol:

(i) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist and available for inspection by a Board Inspector upon request.

(ii) Written protocols, including standard protocols, any patient specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the practitioner and pharmacist at least annually and revised, if necessary. Such review shall be documented in the pharmacist's records. Documentation of all services provided to the patient, by the pharmacist, shall be reviewed by the physician on the schedule established in the protocol.

(iii) Any protocol from a practitioner shall be maintained in the pharmacy and available for inspection by a Board Inspector upon request.

(D) Confidentiality:

(i) A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is not transmitted directly between a pharmacy and a practitioner, but is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this regulation.

(ii) Confidential records are privileged and may be released only to:

(a) the patient or the patient's agent;

(b) practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;

(c) other persons, the Board, or other state or federal agencies authorized by law to receive such information;
(d) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act; or
(e) a person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person's official duties.

(iii) This regulation shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act.

09-01: DISEASE STATE MANAGEMENT

09-01-0001—AREAS OF PRACTICE IN DISEASE STATE MANAGEMENT

The Board of Pharmacy will recognize the following areas of practice in Disease State Management. This list may be expanded, as standard exams in other areas become available.

(a) Asthma
(b) Anticoagulation therapy
(c) Diabetes
(d) Dyslipidemia

09-01-0002—QUALIFICATIONS, RESOURCES, AND RECORD KEEPING REQUIRED FOR PRACTICING IN A DISEASE STATE MANAGEMENT AREA IN ARKANSAS.

(a) To obtain a credential in an area of disease state management a pharmacist must meet the following qualifications:
  (1) Be a licensed pharmacist in the State of Arkansas
  (2) Achieve a passing score on an examination approved by the Board of Pharmacy that tests for the minimum standards of competency as identified in Section 09-01. The examination shall be the nationally recognized standard as approved by the Arkansas State Board of Pharmacy.
  (3) Achieve a passing score on an Arkansas State Board of Pharmacy approved practical examination in the area of disease state management.
  (4) Complete requirements for the credential as established by a Board of Pharmacy approved credentialing organization.
(b) Resource requirements for the provision of disease state management services shall include—but are not limited to the following:
  (1) Maintain a distinct area that provides privacy for the provision of disease state management services;
  (2) Maintain references that include a current copy/edition of applicable national practice guidelines and such other resources as may be necessary for the provision of optimal care;
  (3) Maintain devices, supplies, furniture, and equipment as may be needed for the provision of optimal care.
(c) Record keeping requirements for disease state management.

The pharmacist, holding a credential disease state management, shall record, maintain, and transfer data essential to the continuity of care and consistent with all applicable state and federal laws and regulations; and these records and all related files shall be available to the Arkansas State Board of Pharmacy inspectors and professional staff upon request. Additionally, a transferable pharmaceutical care record is to be maintained and is to include:

(1) The written request for consultation from the patient's physician;
(2) The physician approved protocol and/or patient care plan, which is to recognize all concomitant diseases and the patient's complete medication history/profile;
(3) Pharmacy progress notes; and,
(4) Laboratory data.

09-01-0003—MINIMUM COMPETENCIES AND STANDARDS TO BE MET BY THE COMPETENCY EXAMINATIONS FOR DISEASE STATE MANAGEMENT

(a) Minimum competencies for pharmaceutical care in all disease state management areas:
   (1) The pharmacist shall be capable of identifying and accessing the patient's current health status, health-related needs and problems, and desired therapeutic outcomes.
   (2) The pharmacist shall be capable of implementing, and evaluating a pharmaceutical care plan that assures the appropriateness of the patient's medication(s), dosing regimens, dosage forms, routes of administration, and delivery systems.
   (3) The pharmacist shall be capable of communicating appropriate information to the patient and/or caregiver and other health care professionals regarding prescription or non-prescription medications and/or medical devices, disease states, or medical conditions, and the maintenance of health and wellness.
   (4) The pharmacist shall be capable of monitoring and documenting the patient's progress toward identified endpoints and outcomes of the pharmaceutical care plan and shall intervene when appropriate.
   (5) Disease state specific competency requirements are revised periodically and are furnished at the time of application for the respective exams or upon request to the Board.

09-01-0004—NOTIFICATION OF CREDENTIAL IN DISEASE STATE MANAGEMENT REQUIRED:

Every pharmacist who receives a credential in disease state management from a Board approved credentialing agency, must mail a copy of the credential to the Board of Pharmacy office, along with proof of satisfactory completion of the practical examination. Upon receipt of the credential and acceptable evidence of successful completion of the Board's practical examination, the Board's Executive Director shall cause the approval of the qualifications for the pharmacist to practice in a disease state management area and the pharmacist shall be qualified to practice in the credentialed disease state management area. The Board of Pharmacy will notify any party requesting notification that the pharmacist is so qualified.

09-01-0005—CONTINUED COMPETENCE

The Arkansas State Board of Pharmacy may require additional training and assessment of pharmacists who hold a credential in that disease state. Sufficient notice, by the Arkansas State Board of Pharmacy, shall be given to the pharmacists holding the credential being redefined. (Adopted 8/19/99, Revised 8/2001)